No. 99956-2

IN THE SUPREME COURT OF THE STATE OF WASHINGTON

CERTIFICATION FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON

IN:

DAVID J. DEARINGER and GANNA P. DEARINGER,
Petitioners-Plaintiffs,

v.

ELI LILLY AND COMPANY,
Respondent-Defendant.

REPLY BRIEF OF PETITIONERS-PLAINTIFFS ON CERTIFIED QUESTION

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I. INTRODUCTION

The Petitioners/Plaintiffs (hereafter "the Plaintiffs") could not say it any better than the late Justice Daniel Joseph O'Hern of the New Jersey Supreme Court, when he wrote for the majority in the *Perez* case:

> Our medical-legal jurisprudence is based on images of health care that no longer exist. At an earlier time, medical advice was received in the doctor's office from a physician who most likely made house calls if needed. The patient usually paid a small sum of money to the doctor. Neighborhood pharmacists compounded prescribed medicines. Without being pejorative, it is safe to say that the prevailing attitude of law and medicine was that the "doctor knows best."

Perez v. Weyth Labs Inc., 161 N.J. 1, 734 A.2d. 1245, 1255 (1999)(citations and some quotation marks omitted).

The good Justice continued to describe the World which gave rise to the advent of the learned intermediary doctrine ("LID"):

> Pharmaceutical manufacturers never advertised their products to patients, but rather directed all sales efforts at physicians. In this comforting setting, the law created an exception to the

> traditional duty of manufacturers to warn consumers directly of risks associated with the product as long as they warned health-care providers of those risks.

Perez, supra.

Justice O'Hern wrote those enlightened words twenty-one years after their sister Court, this Washington Supreme Court, had the occasion to adopt the LID for our State in the case of *Terhune v. A.H.Robins Co.*, 90 Wn.2d 9, 577 P.2d 925 (1978).

The LID created an exception to the general rule of tort law that a product manufacturer must provide the ultimate consumer adequate warning of the inherent dangers of the manufacturer's product. [1/] If that product manufacturer happens to be a "prescription drug or device" manufacturer, it is permitted under the LID for such manufacturer to provide the warning only to the *doctor* of the ultimate consumer.

[1/] See *e.g.* Washington's Product Liability Act RCW 7.72.010 *et seq.*

The reason why the Eighth Circuit created this special exemption for prescription drug or device manufacturers is because:

> If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided. This is particularly true if the injury takes place slowly, as is the case with the injury in question here.

Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir.1966). Thus we can clearly see that the LID was born because "there is an excellent chance that injury to the patient can be avoided" if only the doctor is warned.

Just as a spark floating onto a dry field of tall sun-bleached grass in July, the LID swept the country like a wildfire. Courts and some legislatures fell under the spell of this new legal concept of the LID.

How could the LID become so popular in such a short time? Perhaps billions of dollars spent on high power lawyers, lobbying and political campaigns had something to do with it. [2/]

The LID certainly has given Big Pharma a financial leg up to protect their interests in the halls of Congress and the various state legislatures.

II. ARGUMENT

A. No one in 1966 expected that Defendant and others of the Pharmaceutical Industry would someday interfere with the Doctor/Patient relationship.

Gone are those great pioneers of industry that cared as much for the public good as they did for the accumulation of wealth. As a child Eli Lilly (1838-1898) developed a love for chemistry by watching the apothecary father of a friend compound the chemicals to produce medicines at the Good Samaritan Drug Store. Eli Lilly grew up to become an abolitionist and fought bravely for the North in the "Lightening

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[2/] Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States, (1999-2018),* 180 JAMA Intern Med (2020) May 1;180(5):688-697.

Brigade" during the American Civil War where he advanced to the rank of Lieutenant Colonel. Lilly, with his son and grandsons, founded many charitable organizations while simultaneously expanding their wholesale drug manufacturing company.

The early Lilly Family would have been appalled to find that the pharmaceutical giant they founded would someday become a company that inserts itself between a patient and his doctor to deceitfully mass market a dangerous recreational drug as a treatment for a fictitious disease that their industry invented in order to create a demand for the PDE_5 inhibitor they discovered by accident. [3/]

In the World as it existed in 1966 drug manufacturers did not stand between the patient and doctor like Defendant does

[3/] Plaintiffs posit that erectile dysfunction (ED) is a natural part of aging rather than a disease. ED was invented by the pharmaceutical industry to create demand for the product (PDE_5) they discovered by accident. The science of Urology began to use the term "erectile dysfunction" rather than simply "impotence" only after PDE_5 became popular from television commercials.

now. This fact was recognized by the Supreme Court of New Jersey, who the Defendant self-servingly abhors:

> . . . with rare and wonderful exceptions, the "Norman Rockwell" image of the family doctor no longer exists . . . Informed consent requires a patient-based decision rather than the paternalistic approach of the 1970s . . . The decision to take a drug is not exclusively a matter for medical judgment . . . because managed care has reduced the time allotted per patient, physicians have considerably less time to inform patients of the risks and benefits of a drug . . . In a 1997 survey of 1,000 patients, the F.D.A. found that only one-third had received information from their doctors about the dangerous side effects of drugs they were taking . . . having spent $1.3 billion on advertising in 1998, drug manufacturers can hardly be said to lack effective means to communicate directly with patients, when their advertising campaigns can pay off in close to billions in dividends.

Perez, supra , at 1255-56 (citations and some quotation marks omitted).

B. The LID incentivizes drug manufacturers to increase sales at the risk of harm the consumer.

The phosphodiesterase-5 enzyme (PDE_5) inhibitor was discovered by accident. Researchers were not actively

searching for a treatment for Erectile Dysfunction (ED) as they were searching for a vaccine to prevent polio back in the 1930s.

The Defendant has chosen to plant its flag on the hill that claims the LID should continue undisturbed because

> DTC advertising does not change the requirement that a patient must obtain a medication through a state-licensed prescriber.

Response of Defendant ("ROD" at page 2). In this age of "doctor shopping" "healthcare rationing" and "competitive practice advertising" where physicians and health insurance plans actively compete for patients, Defendant is well aware of the adversarial climate existing within the medical profession today. If a patient's doctor won't prescribe for him a PDE_5 inhibitor, he will simply search for a doctor that will. The doctor/patient relationship is no longer static; it is dynamic. Patients now have more healthcare mobility now than they ever had back in 1966 or even 1978.

When the State of Washington adopted the LID, it did so with a case involving injuries caused by the contraceptive device, the "Dalkon Shield." The injured parties:

> *sought advice from their family physician* . . . regarding available methods of contraception. He informed them of the advantages and disadvantages of various methods, and they chose the Dalkon Shield.

Terhune v. A. H. Robbins, 90 Wn.2d 9, 10, 577 P.2d 975 (1978)(emphasis added). The plaintiffs in Terhune didn't find the Dalkon Shield on a television commercial in the same way consumers of PDE_5 found Cialis. In *Terhune* the plaintiffs "sought advice from their family physician" and that physician told them about the various contraception methods available after which "they chose the Dalkon Shield."

The LID was never intended to shield companies that mass market their products.

C. Companies like the Defendant are using their special common law status to abuse the system.

The Defendant's legal strategy is to ignore the scientific evidence that PDE_5 inhibiters cause intracerebral hemorrhage (ICH) and then blame physicians under the LID for prescribing Cialis to vulnerable patients.

Defendants contend that:

> Serious cardiovascular events, including myocardial infarction, sudden cardiac death, stroke, chest pain, palpitations, and tachycardia, have been reported postmarketing in temporal association with the use of tadalafil [Cialis].

ROD, at pages 6-7. The Defendant also recommends "physicians to consider the cardiovascular status of their patients because of the cardiac risk associated with sexual activity." *Id*.

Defendants expect that because it used the word "stroke" within the context of "serious cardiovascular event" it provided "adequate" warning for intracerebral hemorrhage (ICH).

As aptly recognized by the distinguished U. S. District Judge Barbara Rothstein (a fellow Washingtonian):

> Hemorrhagic stroke results from the rupturing of a blood vessel in the brain. The hemorrhage may be either intracerebral (within the brain itself) or subarachnoid (within the fluid-filled space surrounding the brain) (hereinafter "ICH" and "SAH" respectively). Approximately fifteen to twenty percent of strokes fall into the hemorrhagic category.
>
> * * *
>
> Ischemic stroke results from the blocking of blood flow in a cerebral vessel, depriving brain tissue beyond the blockage of oxygen. The vast majority of strokes are ischemic.

In re Phenylpropanolamine (PPA) Prods. Liab. Litig., 289 F.Supp.2d 1230, 1238 (W.D.Wash. 2003).

Not all "strokes" are the same. Some are "blockages" (ischemic) and others are "bleeds" (hemorrhagic). Plaintiff David J. Dearinger had a bleed, like the one warned of by the scientific community, but concealed by Defendant.

D. Defendant misleads the Court about the certified record

Defendant states that the Complaint fails to mention DTC advertising:

> there are no allegations in the complaint relating to DTC advertising.

ROD at page 11.

Yet Plaintiffs' Complaint states the following:

> Since Cialis's FDA approval in 2003, Defendant has engaged in a continuous and expensive multimedia advertising campaign to market Cialis to men worldwide as a symbol of regaining and enhancing one's virility.

First Amended Complaint (Dkt. 10) at page 5, paragraph 4.9.

Defendant may have unintentionally overlooked this paragraph but it is more likely to be an indication of Defendant's larger legal strategy of deception and concealment.

The Defendant completely ignores the Appendix section of the Plaintiffs' opening brief where Plaintiffs provide the scientific evidence to prove Defendant's intentional

concealment alleged in the Complaint [4/] that addresses the scientific studies that prove that the PDE_5 inhibitor causes intracerebral hemorrhages (ICH).

E. The Defendant refuses to address its concealment of the dangerous side effect of intracerebral hemorrhage from its product

The LID gave the pharmaceutical industry the incentive to conceal the dangerous side effect of intracerebral hemorrhage (ICH). Product liability lawyers are fearful of suing drug manufacturers because of the LID. Defendant knows this and used this fact to conceal the side effect of ICH. Evidence of this fact is the refusal of the Defendant to address this allegation in its response to this Court.

The LID emboldens the industry to exploit this special status the Courts have given them beginning with *Sterling Drug, Inc. v. Cornish*, supra. Lawyers can't afford to fight drug manufacturers because of the LID.

[4/] Paragraphs 4.5 to 4.8 of Plaintiffs' First Amended Complaint (Dkt. 10, Certified Record) pages 4-5.

F. The Defendant wants this Court to blame physicians for their own malfeasance.

Defendant [5/] tells the Court that licensed physicians are responsible for prescribing its product yet the Defendant sends a message in its television commercials that patients must throw caution to the wind and demand that their doctors prescribe the Cialis Fountain of Youth and them blame the doctors when something goes wrong.

The Defendant's message to the consumer is that there is a world of young women out there just waiting for you and all you have to do is take this pill. The subsequent media sensation was predictably fruitful. Legions of middle-aged males began to line up outside their urologists' offices to receive prescriptions for the beige, blue, or yellow pill. In fact many consumers obtained the pill from Canadian telemarketers WITHOUT a prescription.

[5/] RAP 10.4(e) provides in pertinent part: ". . . It promotes clarity to use the designations used in the lower court, [or] the actual names of the parties . . .."

Doctors are not the problem in America: untempered corporate greed is the problem. Eli Lilly and Company is asking the Court to allow it to continue blaming licensed physicians for prescribing the drug for which it alone created the demand.

The Point of Sale

People that work in retail sales use a term called P-O-S that means "Point of Sale" (hereinafter "POS") which is distinguished from "Point of Purchase." POS is where a consumer makes the decision to purchase something; alternatively "Point of Purchase" is where the purchase is made (usually at a cash register) and the exchange of money transpires.

When we drive our cars into a convenience store or fast-food parking lot we see POS everywhere; Pictures to make us hungry, thirsty, or whatever condition that could compel us to decide to purchase more than what we originally intended. At the precise moment our eyes view a large photograph of our

favorite food or beverage item, quite often we make a decision to purchase that item even though our original purpose for leaving the house was to purchase AA batteries for our television's remote control unit. Those photographs are the "Point of Sale" because the image caused the decision of the consumer to decide to buy the product.

The thirty-second television commercials that advertise Cialis is the Defendant's POS. By the time patients ultimately arrive at their scheduled appointments with their urologists they have already made to decision to purchase Cialis because the patient has already made a dinner date with a young woman that looks like the one wearing a bikini in the Cialis commercial.

We are now in the age of doctor shopping. Patients, depending on where they live, can chose their health plan based upon what medications doctors are willing to prescribe and

chose their insurance accordingly. Doctors now compete for patients. [6/]

Maybe in a perfect world, like the world envisioned in 1966 when the Learned Intermediary Doctrine ("LID") entered America's legal lexicon, [7/] in which the Pharmaceutical Industry acts responsibly, however that world no longer exists.

The LID began under the assumption that the Pharmaceutical Industry would *not* conceal the dangerous side effects of their products. In this instance the Defendant Eli Lilly and Co. (Respondent) knew since 2001 that their product causes Intracerebral Hemorrhage (ICH), yet Defendant calculated correctly that the LID would cause most tort lawyers would be too scared to sue drug companies out of fear from

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[6/] See *e.g.* Medibid ("Reducing Healthcare Costs Through Competitive Bidding"), https://www.medibid.com (last visited November 12, 2021).

[7/] *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir.1966).

going bankrupt if they take on the protected drug companies. [8/] Defendant and others in the Pharmaceutical Industry took the example of from the Tobacco Industry

The Defendant was being uncommonly truthful when it stated that: "It is no accident that every state's tort law mirrors" the LID. (ROD at 1)

Plaintiffs, in their opening brief (at page 33), list the annual gross revenue earned by Defendant just from sales of Cialis *alone*, which provides Defendant with a substantial war chest for lobbying Congress and the various state legislatures to maintain their cash cow. [9/] Of course it is no accident.

The dedicated, hard-working janitors that work nights in fifty state capitols spend many hours buffing out the scuff-

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[8/] Plaintiffs document the difficulty they faced in finding an attorney to represent them in their Motion and Declaration to Appoint Counsel in the court below. (Dkt. 19).

[9/] See Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States*, (1999-2018), 180 JAMA Inter. Med. 688 (2020).

marks made from the shoes of the Defendant's army of lobbyists to insure that the LID stays on the books.

The legal profession considers every case against drug companies to be a lost cause which is exactly the way Defendant wants it. Every lawyer Petitioners spoke with considers drug companies to have an unfair advantage over the ones that were injured by Big Pharma.

The first phosphodiesterase type 5 enzyme ("PDE_5") inhibitor was approved by the FDA in 1998. Defendant's product Cialis secured FDA approval in 2003. During the two decades between the years 1999 and 2018 the Defendant's industry expended $4.7 billion on lobbying to influence election and legislative outcomes at just the federal level, more than any other industry. [10/]

This honorable Court can balance the scale by holding the Defendant accountable for its tortuous conduct.

[10/] Wouters, *supra*.

G. The Defendant wants to berate New Jersey as inept bumpkins for resisting the LID

While Defendant boasts that 52 jurisdictions recognize the LID the protect the pharmaceutical industry it is important to keep in mind that Big Pharma spends billions of dollars on lobbyists and political campaigns.

The Supreme Court of West Virginia followed the lead of New Jersey in *State ex rel. Johnson & Johnson v. Karl*, 220 W.Va. 463, 647 S.E.2d 899 (2007), but then Big Pharma parachuted scores of their lobbyists onto the capitol city Charleston causing their Assembly to adopt W. Va. Code § 55-7-30(a).

H. Pro Se Litigation Must Be Held to a Less Stringent Standard

Courts in Washington are seeing a trend of increased *pro se* representation and are responding in accordance with that trend. See *e.g.* "The *Pro Se* Handbook: A Guide to

Representing Yourself in King County Superior Court." (2006), King County Bar Association. [11/]

The federal courts have a policy to hold *pro se* litigation "however inartfully pleaded," "to less stringent standards than formal pleadings drafted by lawyers." *Haines v. Kerner*, 404 U.S. 519, 520, 92 S. Ct. 594, 30 L. Ed. 2d 652 (1972)(per curiam), reh'g denied, 405 U.S. 948 (1972). See also *Tatum v. Christensen*, 786 F.2d 959, 963 n.4 (9th Cir. 1986)(per curiam)(court can "reach merits without determining whether the form was correct"); *Bretz v. Kelman*, 773 F.2d 1026, 1027 n.1 (9th Cir. 1989)(en banc)(court has obligation to construe pro se pleadings "liberally and to afford the petitioner the benefit of any doubt").

The appellate courts in Washington State have rejected the said policy. See *Marriage of Olson*, 69 Wn. App. 621, 626, 850 P.2d 527 (1993)(Division One); *Edwards v. Le Duc*, 157 Wash.App. 455, 238 P.3d 1187, 1190 (2010)(Division Two);

[11/] http://www.kcba.org/kcba/publications/pdf/pro-se2006.pdf (last visited November 9, 2021).

Batten v. Abrams, 28 Wn. App. 737, 739 n.1, 626 P.2d 984 (Division Three), *review denied*, 95 Wash.2d 1033 (1981); *cf. Carver v. State*, 147 Wash.App. 567, 575, 197 P.3d 678 (2008)(Division Three provides an exception "when a *pro se* plaintiff . . . suffers from a significant mental disability").

Plaintiffs are on record that they tried to obtained counsel to represent them in this case, but because of the LID no attorney they spoke to could overcome their fear of prescription drug manufacturers. (Dkt. 19).

Plaintiffs suggest that the example of the federal courts to relax the standards for *pro se* litigants would make the courts more accessible for indigents who cannot afford counsel.

VI. CONCLUSION

Drug manufactures use the LID to their advantage. They don't play fairly because they don't have to. The LID keeps their potential adversaries at bay .

Now is the time to revisit the LID to determine whether it is appropriate for the Twenty-First Century.

If both the doctors and the drug companies would have the duty to warn the ultimate consumer of side effects, everyone wins. Fewer consumers would be paralyzed. There is no downside.

DATED: This 22nd day of November, 2021.

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to RAP 18.17(b) Plaintiffs hereby certify that this document contains 3,291 words, exclusive of the title page, table of contents, table of authorities, signature blocks, certificate of compliance, certificate of service, and appendix.

DATED: This 22th day of November, 2021.

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CERTIFICATE OF SERVICE

I certify that, on this day, I sent a copy of this document via e-mail (by agreement under RAP 18.5(a) and CR 5(b)(7)) to the attorneys for the Respondent:

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I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct.

DATED: This 22nd day of November, 2021at Lake Stevens, Washington.

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